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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/920,272	08/22/97	MILLER	F 21.451-B

HM11/0330

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EXAMINER	
TENG,S	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/30/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/920,272	Applicant(s) Miller et al.
	Examiner Sally Teng	Group Art Unit 1646

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) *12-20* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11, 21, and 22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-22* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 21, and 22, drawn to precursor cells of a mammalian peripheral tissue, classified in class 435, subclass 325.

II. Claims 12 and 13, drawn to drawn to a method of treatment, classified in class 424, subclass 93.1.

III. Claims 14-20, drawn to a method of isolating and purifying precursor cells, classified in class 435, subclass 378.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as to isolate a sensory receptor expressed by the precursor cells.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to isolate precursor cells from tongue of a mammal.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions II and III are different inventions because they require different method steps for accomplishing different goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the search required for one group is not required for the others, restriction for examination purposes as indicated is proper.

During a telephone conversation with attorney Patrick Kelly on March 10, 1998, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11, 21, and 22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It has not been signed by the inventors.

3. Claims 1-7, 11 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it seems that the mammal is from peripheral tissues containing sensory receptors. It is suggested that the claim be amended to describe precursor cells from peripheral tissues of mammals.

Claim 9 is vague and indefinite because it is not clear as to what is meant by cells containing dopaminergic neurons. Are the precursor cells differentiated into dopaminergic neurons?

In claims 2-11, 21, and 22, the recitation of "the cells of claim 1." Are they the precursor cells or the stem cells and progenitor cells?

4. Claims 1, 3-11, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for precursor cells isolated from olfactory epithelium of a mammal, does not reasonably provide enablement for precursor cells from the peripheral tissue of any mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to precursor cells isolated from any mammalian peripheral tissue containing sensory receptors. However, the specification only discloses isolation and characterization of precursor cells from the olfactory epithelium. The specification teaches that the precursor cells obtained from olfactory epithelium express glutamic acid-decarboxylase, can be differentiated into neurons and oligodendrocytes, and used as a source of dopaminergic neurons. It is not predictable that precursor cells can be isolated from other peripheral tissues and can be used in a similar manner as precursor cells isolated from olfactory epithelium. It is also not predictable that precursor cells from other peripheral tissues have the same characteristics as the precursor cells from the olfactory epithelium. In fact, the specification does not teach whether the precursor cells from tongue express glutamic acid-decarboxylase, can be differentiated into neurons, astrocytes, and oligodendrocytes, and used as a source of dopaminergic neurons. The specification teaches isolation of precursor cells from tongue, but does not characterize these precursor cells to enable the skilled artisan to use them in a similar manner as the precursor cells from the olfactory epithelium. It is also pointed out that the specification discloses the precursor

cells of the olfactory epithelium differentiated into neurons and oligodendrocyte and the precursor cells of the olfactory epithelium could not differentiate into astrocytes. The specification does not provide sufficient guidance to enable the skilled artisan to predict the physical and functional characteristics of cells grown in culture, especially after they have been passaged and differentiated. *In vivo* cells are structurally and functionally distinct from *in vitro* cells. They are cultured in different environment and are exposed to different growth factors and nutrients. It is not predictable that precursor cells from any peripheral tissue would be able to express neuronal markers and be used as a source of dopaminergic neurons or can be differentiated into neurons, oligodendrocytes, and astrocytes expressing specific markers and genes. Moreover, isolation of precursor cells from peripheral tissues is not taught by the prior art. Accordingly, it would require undue experimentation of the skilled artisan to make and/or use precursor cells from peripheral tissues.

Claim 21 is directed to cells of claim 1 or neurons, astrocytes, or oligodendrocytes differentiated from the cells of claim 1, in a kit for the treatment of a disease, disorder, or abnormal physical state, and claim 22 is directed to the cells of claim 1 for different uses. As explained above, the structural and functional characteristics of precursor cells of peripheral tissues and of neurons, astrocytes, or oligodendrocytes that they differentiate into are not predictable. Neither the specification nor the prior art has ~~not~~ provided sufficient guidance to enable the use of precursor cells obtained from any peripheral tissue recited in claims 21 and 22. It is not known as to what diseases they would be able to treat or what genes the cells would

express. Therefore, the skilled artisan would not be able to use them to treat diseases or disorders, to use them in drug assays, or to isolate genes involved in cell differentiation from them.

Accordingly, due to the lack of guidance from the specification and from the prior art and due to the unpredictable nature of the claimed invention, it would require undue experimentation of the skilled artisan to make and/or use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally Teng, Ph.D., whose telephone number is (703) 308-4230. The examiner can normally be reached on Mon.-Fri. from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957.

Official papers filed by fax should be directed to (703) 305-3014. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 29, 1998

Sally Teng

SALLY TENG
PRIMARY EXAMINER